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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,666	03/18/2004	Yuen-Liang Lai	5482-2	6009

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COHEN, PONTANI, LIEBERMAN & PAVANE
Suite 1210
551 Fifth Avenue
New York, NY 10176

EXAMINER	
PAK, JOHN D	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,666	LAI ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-10 are pending in this application. The claims have not been amended. This Office action is in reply to applicant's response, which was filed on 12/13/2006.

It is again noted for the record that the Examiner is interpreting the phrase "cutaneous metastatic cancer" to mean cancer that has metastasized to cutaneous sites. Said phrase does not mean cutaneous cancer that has metastasized to other sites.

It is also again noted for the record that claim 10 recites a total radiation dose ranging from 30-50 Gy/5 days. In the absence of further clarifying claim language, the Examiner interprets this dose to include 5 non-consecutive days, i.e. a fractionation schedule wherein total of 30-50 Gy is administered on 5 days, but not necessarily on 5 consecutive days.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-10 stand rejected under 35 U.S.C. 102(a) as being anticipated by Lai et al.[1] for the reasons of record.

Applicant argues that this ground of rejection should be withdrawn because of the evidenced provided in the Rule 132 declaration filed on 12/13/2006. The Examiner

cannot agree because the declaration actually makes the issue of inventive entity, authorship and/or attribution even more confusing.

The declaration states that the following four persons are the "original sole inventors and applicants" of the instant claimed invention: Yuen-Lian Lai, Yu-Jen Chen, Yu-Fang Hu and Chi-Liang Kan. Applicant's representative argues in the remarks of 12/13/2006 that those same four persons are "the true and only inventors of claims 1-10 of the present application."

The problem is that the original declaration filed on 8/3/2004 lists one more person, Kuang-Chun Chiu, as a joint inventor. Therefore, attributing the article by Lai et al. as being derived from 4 out of the 5 joint inventors actually operates to attribute the article as being derived by another within the meaning of 35 USC 102(a). Consequently, said article has not been shown to be derived from applicant's own work, and the article is still applicable as prior art under 35 USC 102(a).

In the interest of compact prosecution, applicant is advised that a rejection under 35 USC 102(f) will be held in abeyance for now since the underlying issues are the same as above.

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[1] Anti-Cancer Drugs, 2003, Vol. 14, pages 825-828. Accepted for publication on 9/2003, so this article does not qualify as prior art under 35 USC 102(b). But the article does qualify as prior art under 35 USC 102(a) because the list of authors is different that the inventive entity of the instant application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellison et al. (US 2004/0115283) in view of Cheng[2], the acknowledged prior art and Wu (US 6,127,688).

Ellison et al. disclose arsenic substances such as arsenic trioxide and arsenic sulfides to possess a variety of beneficial anticancer properties, including apoptosis activity, angiogenesis inhibiting activity, differentiating activity, and sensitization of cancer cells to radiation and/or chemotherapy (paragraphs 0031, 0042). Treating primary and metastatic cancers is taught (paragraph 0029), including breast, lung, colon, head and neck cancer in combination with radiotherapy (paragraphs 0030, 0049). More specifically, effective treatments of squamous cell carcinoma, basal cell carcinoma, melanoma, tumors of breast, lung carcinoma and colon carcinoma are disclosed (paragraphs 0051-0053, 0074, 0129). Treatment of metastatic breast cancer and "metastases from breast ... cancer" are disclosed, as well as alleviating or reducing symptoms thereof (paragraph 0103). Any mode of administration of the arsenic substance is disclosed, including topical administration, dermal administration and

transdermal patches (paragraphs 0047, 0110). Colloidal suspensions, creams, ointments, pastes are disclosed for arsenic formulation types (paragraph 0048). Arsenic dosage is taught to vary with the severity of the condition to be treated and route of administration, body weight, age, condition and response of the patient (paragraph 0121). Daily dose of 10 μg to 200 mg, including 0.5 mg to about 70 mg of an arsenic active ingredient is disclosed (id).

Cheng et al. establish that breast cancer commonly affects the skin and cutaneous metastases frequently recur in chest wall or scalp (first English sentence). Cheng et al. disclose a topical formulation of arsenic trioxide for treatment of skin lesions metastasized from the breast (first English paragraph). Clinical evidence of improved dryness of skin lesions and reduced unpleasant odor is reported (first English paragraph, near the end on second English page). Systemic absorption of topically applied arsenic lotion could not be observed (id.).

Applicant acknowledges the following in the instant specification:
(1) Arsenic trioxide is known to inhibit growth of many cancer cell lines and promote apoptosis in the cancer lines (page 3, lines 11-13);
(2) Arsenic trioxide is known to sensitize human cervical cancer cells to ionizing radiation in vivo and arsenic trioxide pre-treatment + ionizing radiation is known to have

[2] Submitted by applicant in the IDS of 9/9/2005.

a synergistic effect with respect to decreased clonogenic survival and regression of established human cervical tumor xenografts (page 4, lines 10-14);
(3) Cheng et al., supra, disclose topical arsenic trioxide to improve local tumor control and decrease wound secretion without significant systemic or local effects (page 4, lines 17-19).

Wu is cited solely to establish that "principal applications" of electron beam radiotherapy are for treatment of skin cancer, head and neck cancer, and chest well irradiation for breast cancer (column 1, lines 24).

Ellison et al. do not expressly disclose treating a human patient having a cutaneous metastatic cancer, e.g. cutaneous metastatic breast cancer, by topically administering to the site of said cutaneous metastatic cancer an arsenic substance such as arsenic trioxide and transcutaneously applying an electron beam to the site, with optional step of removing the arsenic substance before applying the electron beam. Ellison et al. also do not expressly disclose a gel arsenic formulation and daily arsenic dose in terms of mg/cm^2. However, for the reasons set forth below, such differences and the claimed invention as a whole would nonetheless have been obvious to the ordinary skilled person in this art.

While Ellison et al. do not expressly disclose treating a human patient having a cutaneous metastatic cancer, e.g. cutaneous metastatic breast cancer, by topically administering to the site of said cutaneous metastatic cancer an arsenic substance such

as arsenic trioxide, Ellison et al. teach treating metastatic breast cancer, effective treatments of squamous cell carcinoma, basal cell carcinoma, melanoma, tumors of breast, lung carcinoma and colon carcinoma are disclosed (paragraphs 0051-0053, 0074, 0129). Ellison et al. teach treating metastatic breast cancer and "metastases from breast ... cancer," as well as alleviating or reducing symptoms thereof (paragraph 0103). Further, Ellison et al. teach that arsenic trioxide provide the advantage of sensitization of cancer cells to radiation and/or chemotherapy (paragraphs 0031, 0042). Topical and dermal administration and myriad topical formulations such as colloidal suspensions, creams, ointments and pastes are further taught by Ellison et al. Hence, the ordinary skilled artisan in this field would have been sufficiently motivated to topically administer arsenic trioxide to cutaneous metastatic breast cancer in combination with radiation therapy in combination with radiation therapy. Gel formulation would have been obvious from the various topical and dermal formulations taught by Ellison et al., including colloidal suspensions, creams, ointments and pastes.

As for the specific use of electron beams, it is noted that principal applications of electron beam radiotherapy are for treatment of skin cancer, head and neck cancer, and chest well irradiation for breast cancer. Therefore, the ordinary skilled artisan would have been motivated to select such radiation therapy for treating cutaneous metastatic breast cancer.

Applicant's claims 8-9 recite arsenic daily dose in mg/cm^2. Simple conversion with the standard average of 1.8 m^2 (18,000 cm^2) for an average 70 kg adult shows that applicant's claimed daily dose range approximates to about 180 mg to 9,000 mg (claim 8) and 900 mg to 2,700 mg (claim 9). Applicant's claim 8 is met by Ellison's daily dose of up to 200 mg. As for applicant's claim 9, Ellison et al. teach that arsenic dosage is to vary with the severity of the condition to be treated and route of administration, body weight, age, condition and response of the patient (paragraph 0121). Therefore, in view of the fact that topically applied arsenic lotion is not systemically absorbed (Cheng et al.), one of ordinary skill in the art would have been motivated to increase the arsenic concentration/dose in the topical or dermal application to treat cutaneous site of cancer. Keeping arsenic low when administered non-topically is important for balancing the anticancer effect of arsenic with the toxicity of arsenic; but given the lack of systemic absorption in topical administration, one having ordinary skill in the art would have been motivated to increase the dose for increased potency. Consequently, applicant's daily dose range as recited in claim 9 would have been fairly suggested by the combined teachings of the prior art.

Lastly, with respect to claim 2, wherein removal of the arsenic pharmaceutical composition from the cutaneous cancer site is required, it is the Examiner's position that such a step would have been a routine step in the transcutaneous application of electron beams, wherein clear and unhindered access to the site is advantageous.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Applicant's arguments relative hereto, filed on 12/13/2006, have been given due consideration but they were deemed unpersuasive. Applicant argues that the requisite motivation, reasonable expectation of success, and suggestion of all the claim limitations have not been shown. The Examiner cannot agree for the following reasons.

Applicant's first and third arguments (response filed on 12/13/2006, page 6, lines 4-18 & page 8, first full paragraph):

Applicant argues that Ellison provides neither specific example (in vivo or in vitro) nor other specific direction with respect to topical administration of arsenic composition. Applicant characterizes Ellison's disclosure of sensitization of cancer cells to radiation and/or chemotherapy as speculation. Applicant concludes that there is insufficient motivation to topically treat cutaneous metastatic cancer patients with an arsenic composition, followed by radiation therapy, particularly because the pharmaceutical is a highly unpredictable art. Relatedly, applicant argues that the combined references fail to disclose all the limitations cited in the claims. Applicant states, "Examiner does not explicitly inform where this missing limitation as to 'cutaneous metastatic cancer' can be found, i.e. is it well-known knowledge, the Examiner's personal knowledge, or disclosed in any other reference?" Applicant continues by arguing that even if the supposedly

missing limitation were identified, the motivation to modify the teachings of Ellison to arrive at the present invention is missing.

Applicant's third argument (response filed on 12/13/2006, see from the last paragraph of page 6 to line 2 of page 8):

Applicant further argues that there is no reasonable expectation of success to modify Ellison based on the secondary references. This argument ties in the lack of in vivo or in vitro test (also made in the first argument) and arsenic being known as a poison and a carcinogenic agent to conclude that the person of ordinary skill in the art would have to "carry out undue experimentation to determine what specific disease can be treated by a specific arsenic composition."

Examiner's rebuttal:

The Examiner cannot agree with any of applicant's arguments. Since addressing any one of applicant's arguments necessitates addressing elements of applicant's other arguments, the following rebuttal will attempt to address all of applicant's arguments in combination.

First, the ground of rejection repeated above provides a full and complete rationale for a proper prima facie case of obviousness.

Second, applicant is in clear error when he argues, "the Examiner admits that the primary reference Ellison does not teach a method of treating cutaneous metastatic cancer" (page 8 of the 12/13/2006 response, lines 4-6). The Examiner admitted to far

less than that. Applicant's argument does not accurately reflect the Examiner's statements of record (page 5 of the previous Office action, emphases added):

> Ellison et al. do not expressly disclose treating a human patient having a cutaneous metastatic cancer, e.g. cutaneous metastatic breast cancer, by topically administering to the site of said cutaneous metastatic cancer an arsenic substance such as arsenic trioxide and transcutaneously applying an electron beam to the site, with optional step of removing the arsenic substance before applying the electron beam.

It is the combination of all the features, which is not expressly disclosed by Ellison et al.

Treating cutaneous metastatic cancer, as claimed, is fairly suggested by the combined teachings of the cited and acknowledged prior art. As already stated above, Ellison et al. teach effective treatments of squamous cell carcinoma, basal cell carcinoma, melanoma, tumors of breast, lung carcinoma and colon carcinoma are disclosed (paragraphs 0051-0053, 0074, 0129). Ellison et al. teach treating metastatic breast cancer and "metastases from breast ... cancer," as well as alleviating or reducing symptoms thereof (paragraph 0103). Treating cancer, such as breast cancer, that has metastasized to cutaneous sites (see Cheng) would therefore have been amply suggested. Further, Ellison et al. teach that arsenic trioxide provide the advantage of sensitization of cancer cells to radiation and/or chemotherapy (paragraphs 0031, 0042) and it has already been acknowledged by applicant that arsenic trioxide is known to have synergistic effect with ionizing radiation in treating cervical cancer. Topical and dermal administration and myriad topical formulations such as colloidal suspensions,

creams, ointments and pastes are further taught by Ellison et al. Hence, the ordinary skilled artisan in this field would have been sufficiently motivated to topically administer arsenic trioxide to cutaneous metastatic breast cancer in combination with radiation therapy, as claimed.

Third, applicant's argument as to lack of specific example or specific direction with respect to topical administration of arsenic, and thus the argument of undue experimentation, is deemed unpersuasive. Treating cancer, such as breast cancer, that has metastasized to cutaneous sites (see Cheng) would have been amply suggested from Ellison's teaching of effective treatments of squamous cell carcinoma, basal cell carcinoma, melanoma, tumors of breast, lung carcinoma and colon carcinoma (paragraphs 0051-0053, 0074, 0129) and metastatic breast cancer and "metastases from breast ... cancer," as well as alleviating or reducing symptoms thereof (paragraph 0103). Ellison's 14 pages of data figures and Tables 1-2 disclose in vitro test results against 57 cancer cell lines. Plus, applicant has admitted that arsenic trioxide is known to inhibit growth of many different cancer cell lines in clinical trials and promote apoptosis in the cancer lines (specification page 3, lines 11-13), arsenic pretreatment is known to decrease clonogenic survival and regression of established human cervical tumor xenografts, and topical arsenic trioxide is known to improve local tumor control and decrease wound secretion without significant systemic or local effects. Plainly,

applicant has ignored the prior state of the art in unduly, erroneously and narrowly interpreting Ellison's teachings.

Fourth, applicant's characterization of Ellison's disclosure of sensitization of cancer cells to radiation and/or chemotherapy as speculation misses wide of the mark. Ellison's disclosure (including claim 9 and those discussed above), taken with applicant's admitted prior art that arsenic is known to have similar sensitizing activity against human cervical cancer cells to ionizing radiation, would have provided additional motivation to utilize arsenic with radiation, as claimed.

Fifth, given the combined teachings of the prior art, as discussed above, there would most certainly have been reasonable expectation of success when modifying Ellison based on the secondary references to arrive at the instantly claimed invention. The poison argument is of little persuasiveness. Most cancer drugs are harmful to patients. It's a balance between killing the cancer cells while holding off the harm to the patient to a tolerable level. Given the known anticancer effect of arsenic trioxide to human cancers, as discussed in full above, there would have been reasonable expectation of success, as required.

Relatedly, applicant makes the argument that "[t]he fact that Ellison limits its claims to treatment of only melanoma, despite the broad disclosure in the specification, seems to suggest that the specification does not fairly suggest or teach the treatment of all of the numerous cancerous diseases mentioned in the specification." This argument

is of plenary unpersuasiveness. The fact that a patent document discloses broadly but claims less says nothing about fair suggestion or teaching. The record will show that the Ellison reference is a publication of 10/649,776, which is a division of an earlier case. The claims of a divisional application tend to be more limited than the claims of the original first application because the subject matter has been divided. Additionally, suppose applicant were to limit the instant claims to arsenic trioxide to overcome rejections, expedite prosecution or simplify issues for appeal. Does this mean that applicant's disclosure no longer "fairly suggest or teach" other arsenic compounds? Clearly, the scope of the claims is not necessarily what is fairly suggested or taught by a broader disclosure of a patent or patent application publication.

Sixth, applicant makes one additional argument, viz. teaching away and unexpected result (see the paragraph bridging pages 7-8 of the 12/13/2006 response). Applicant argues that treatment of cutaneous metastatic cancer with radiation therapy or chemotherapy is "disappointing," which would have discouraged the ordinary skilled artisan from applying radiation therapy to a cutaneous metastatic cancer patient after treatment with an arsenic composition. In other words, applicant argues that the present invention would have been unexpected to a person of ordinary skill in the art.

However, the secondary reference by Cheng et al. clearly discloses good clinical results with arsenic trioxide topical formulation in treating skin lesions metastasized from the breast, and applicant acknowledges the same (specification page 4, lines 17-19).

Hence, results asserted to be "unexpected" must be evaluated in the context of expected results from Cheng's teachings and the known "principal applications" of electron beam radiotherapy for treating skin cancer and chest well for breast cancer (Wu). Further, evidence of nonobviousness, if any, must be commensurate in scope with that of the claimed subject matter. In re Kulling, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Lindner, 173 USPQ 356, 358 (CCPA 1972). Here, even though the claims read on any arsenic-containing composition of any structure and any total radiation dose of any fractionation schedule, applicant's specification results are limited to 0.01-0.5 mg/cm^2/day arsenic trioxide administered 1 hour prior to daily electron beam radiation treatment, at 5 days a week, 50 Gy in 25 fractions or 30 Gy in 10 fractions. Applicant's test data, even if it were unexpected based on what would have been expected as discussed above[3], is clearly not commensurate in scope with that of the claimed subject matter since structurally divergent arsenic compounds and different doses of arsenic and radiation (amount and schedule) would be expected to deliver different result. Since such different results have not been provided, it cannot be determined whether such results would have been unexpected.

[3] The burden of establishing unexpected result is on applicant, and the burden has not been met, as discussed above,

For these reasons, all of applicant's arguments are found unpersuasive and this ground of rejection must be maintained.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellison et al. (US 2004/0115283) in view of Cheng, the acknowledged prior art, Medline abstract 95357499, Medline abstract 84139233, and Wu (US 6,127,688) for the reasons of record.

Teachings of Ellison et al., Cheng et al., the acknowledged prior art, and Wu have been discussed in the preceding ground of rejection, and the discussion there is incorporated herein by reference.

The two Medline abstracts are cited to establish the obviousness of the total radiation dose of 30-50 Gy/5 days (claim 10).

Medline abstract 95357499 discloses accelerated radiotherapy to have the potential to increase local control of rapidly growing tumors. 2 Gy per fraction, 8 hours between fractions, for a total of 50 Gy is disclosed for treatment of breast cancer patients. This calculates to 6 Gy per day and 30 Gy/5 days.

Medline abstract 84139233 discloses large dose of irradiation to provide beneficial anticancer results. Disclosed is 10 Gy at 3 times a week for a total of 30 Gy by betatron electron in advanced breast cancer. This equals 30 Gy/3 days.

Complete rationale for obviousness of claims 1-9 has been set forth in the preceding ground of rejection, and the discussion there is incorporated herein to avoid repetition. Claim 10 differs from the cited references in that no one single reference specifically discloses arsenic + electron beam transcutaneously applied in a total radiation dose of 30-50 Gy/5 days to treat a human patient having a cutaneous metastatic cancer. However, except for the specific total radiation dose, the rest of the invention feature has already been discussed as being obvious for the reasons stated above. With respect to a total radiation dose of 30-50 Gy/5 days, the two Medline abstracts establish that accelerated radiotherapy for breast cancer treatment, total dose up to 50 Gy, and 30 Gy/5 days are all known treatment techniques to aggressively treat breast cancer, advanced cancer in particular. One having ordinary skill in this art is a highly skilled and educated physician with at least an MD and/or PhD, with a specialty in oncology and/or radiation oncology. To such an ordinary skilled artisan in this field, 30-50 Gy/5 days would have been an obvious and routine optimization of fractionation schedule to aggressively treat metastatic cancer that has invaded cutaneous sites, particularly when there are few other viable treatment options left. Motivation to optimize arises from the known benefit of accelerated radiotherapy and larger doses of radiation to treat advanced cancers.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because

every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Applicant does not separately argue this ground of rejection – applicant's arguments with respect to this ground of rejection is the same as the arguments presented for the previous ground of rejection under 35 USC 103(a). The Examiner's rebuttal arguments set forth in said previous ground of rejection are incorporated herein by reference.

For these reasons, all claims must be rejected again.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John Pak
Primary Examiner
Technology Center 1600